510(k) SUMMARY

Rusch Safety Silk Tracheal Tube Series

Name, Address, Phone and Fax Number of Applicant

Teleflex Medical, Incorporated
2917 Weck Drive
Research Triangle Park, NC 27709 USA
Phone: 919-491-8960
Fax: 919-433-4996

Contact Person

Lori Pfohl
Regulatory Affairs Specialist

Date Prepared

6/3/2014

Device Name

Trade Name: **Rusch Safety Silk Tracheal Tube Series**

Common Name: Tracheal Tube

Classification Name: Tube, Tracheal (Class II per 21 CFR 868.5730, Product Code BTR)

Predicate Devices

Teleflex Medical's Rusch Oral/Nasal (Safety Clear Plus) Tracheal Tube Cuffed, Magill/Murphy – K993786

Teleflex Medical's Rusch Oral/Nasal Tracheal Tube Cuffed, Magill/Murphy – K961837

Device Description

The proposed Teleflex Medical **Super Safety Silk and Nasal Safety Silk** tracheal tubes are sterile, single use devices that are made from Polyvinyl chloride (PVC) resin that is formulated without DEHP ("Non-DEHP" = < 0.1% DEHP w/w). The tracheal tubes contain a compatible cuff, inflation line, pilot balloon and one-way valve. A radiopaque line is incorporated into the full length of the tracheal tube. Each tracheal tube is supplied with an appropriately sized 15mm connector.

The oral version of the device (Super Safety Silk) will be sold in both Murphy eye and Magill styles.

The nasal version of the device (Nasal Safety Silk) will be offered in the Murphy eye style only.

Indications for Use

- Rusch tracheal tubes are indicated for oral or nasal intubation for airway management.

Intended Population
- Adults

Intended Environment of Use
- Locations where ET intubation may be performed.

Contraindications
None

Substantial Equivalence
The proposed device is substantially equivalent to the predicate devices:

Features	Teleflex Medical Safety Silk Series Oral / Nasal Tracheal Tube (proposed)	Teleflex Medical Oral / Nasal Tracheal Tube (Safety Clear Plus) (K993786)	Teleflex Medical Oral / Nasal Tracheal Tube (K961837)
Classification Name	Tube, Trachea (w/wo connector)	Same	Same
Product Code	73 BTR	Same	Same
Regulation Number	868.5730	Same	Same
Indications for Use	Rusch tracheal tubes are indicated for oral or nasal intubation for airway management.	Rusch Oral / Nasal Trachea Tube, Cuffed, Magill/Murphy is a device inserted into a patient's trachea via the nose or mouth and used to maintain an open airway.	Oral or nasal intubation and airway management

Features	Teleflex Medical Safety Silk Series Oral / Nasal Tracheal Tube (proposed)	Teleflex Medical Oral / Nasal Tracheal Tube (Safety Clear Plus) (K993786)	Teleflex Medical Oral / Nasal Tracheal Tube (K961837)
Environment of Use	Locations where ET intubation may be performed	Not stated	Not stated
Patient Population	Adults	Not stated	Not stated
Contraindications	None	Same	Same
Single Use	Yes	Same	Same
Size Range	5.0 mm – 10.0 mm	2.0 mm – 4.0 mm	4.5 mm – 11.0 mm
Cuffed	Yes	Same	Same
Radiopaque	Yes	Same	Same
Connection to ventilation source	15 mm connector	Same	Same
Method of Sterilization	Ethylene Oxide 10^{-6} SAL	Same	Same
Biocompatibility	Materials have been tested per ISO 10993	Same	Same
No-DEHP	Yes	No	No
Packaging Configuration	Ten (10) individual units in a shelf box. Ten shelf boxes in a shipper		
Sterile	Yes	Same	Same
Eye	Murphy and Magill	Same	Same
Tip	Beveled	Same	Same
Graduations	Multiple cm markings	Same	Same
Shaft	PVC	Same	Same
Cuff	PVC	Same	Same
Pilot Balloon	PVC	Same	Same
Inflation Valve	PVC	Same	Same
Inflation Tube	PVC	Same	Same
X-Ray Marker, Stripe	PVC with Barium Sulfate	Same	Same
Connector	Polyamide	Polypropylene	Polypropylene

Comparison to Predicate Device:

The proposed Safety Silk series tracheal tubes are substantially equivalent to the predicate devices with respect to indications for use, technology and construction. The proposed device is designed with different materials than the predicate. These proposed device materials are Non-DEHP.

- **Indications for Use –**
  The indications for use are substantially equivalent for the proposed device when compared to the predicates. Each device is indicated for Oral or Nasal use in airway management.

- **Technology and construction -**
  The design, fabrication, shape, size, etc. are substantially equivalent to the predicates. This design includes the disposable tracheal tube, cuff side arm assembly and 15mm connector.

- **Environment of use –**
  While not specifically stated, the environments of use are equivalent to predicates

- **Patient Population -**
  While not specifically stated, the patient population is equivalent to the predicate

- **Materials -**
  All patient contacting materials are in compliance with ISO 10993-1. Testing included Cytotoxicity, sensitization, intracutaneous activity, implantation and genotoxicity testing.

Performance Testing

Test	Reference to Standard (if applicable)	Principle of Test	Acceptance Criteria
Cuff Bonding Leak Evaluation	N/A	To perform a visual check at the welding point of the cuff	No leak around the welding area
Tube Curvature Test	ISO 5361	To measure the curvature of the tube	Must meet the product requirement of 140mm ± 20mm
Tube Collapse	ISO 5361	The patency of the ET tube airway lumen is tested by passing a steel ball through the tracheal tube lumen with the cuff inflated within a transparent tube	The steel ball (OD = 75% of the stated ID) must pass through the lumen freely.
Cuff Resting Diameter	ISO 5361	The resting diameter of the cuff is measured when the cuff is inflated to a reference pressure which is intended to remove creases but minimize stretching of its walls	The cuff resting diameter shall be within ± 15% of specification for each individual size
Test	**Reference to**	**Principle of Test**	**Acceptance Criteria**

	Standard (if applicable)		
Cuff Herniation	ISO 5361	The tendency of the cuff to herniate beyond the plane perpendicular to the long axis of the tube at the nearest edge of the bevel is tested by applying an axial force with the cuff inflated within a transparent tube. A cuff which protrudes excessively at its patient end may partially or completely occlude the orifice at the patient end	No abnormality or defect on the cuff (any part of the inflated cuff reaches beyond the nearest edge of the bevel will be considered as defect). No abnormality on the configuration of the cuff during deflating the cuff over a period of not less than 10s (any abnormality will be considered as defect)."
Side Arm Bonding Strength	N/A	To evaluate the retention force of the inflation line connection to the Tracheal tube	Must be able to sustain a minimum of 15N
Connector Bonding Strength	N/A	The security of the attachment of the connector to the tracheal tube is tested by applying an axial separation force to the connector	Tube-Connector bonding must meet the minimum specification to 50N
Tube Compression Evaluation	N/A	To measure the rigidity of the tube	Must be within the range of current data
Cuff Unrestrained Burst Evaluation	N/A	To determine minimum cuff burst pressure under unrestrained conditions	Must be within the range of current data
Cuff Restrained Burst Evaluation	N/A	To determine cuff burst volume under restrained conditions to simulate conditions in the trachea	Must be within the range of current data
Cuff Sealing Pressure Evaluation	N/A	To determine the minimum cuff pressure required to seal the corrugated tube	Must be within the range of current data

The **Rusch Safety Silk Tracheal Tube Series** has the same indications for use, technological characteristics and construction as its predicates. Performance test results demonstrate that the proposed device is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 6, 2014

Teleflex Medical, Incorporated
Ms. Lori Pfohl
Senior Regulatory Affairs Specialist
2917 Weck Drive
Research Triangle Park, NC 27709

Re: K132415
Trade/Device Name: Rusch Safety Silk Tracheal Tube Series
Regulation Number: 21 CFR 868.5730
Regulation Name: Tracheal tube
Regulatory Class: II
Product Code: BTR
Dated: May 05, 2014
Received: May 06, 2014

Dear Ms. Pfohl:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

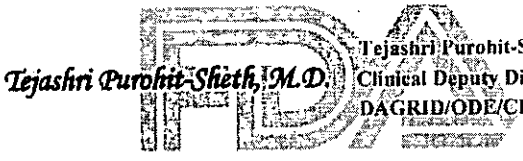
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K132415

Device Name
Rusch Super Safety Silk Tracheal Tubes

Indications for Use *(Describe)*

Rusch tracheal tubes are indicated for airway management by oral or nasal intubation of the trachea.

Intended Population: Adults

Intended Environment of Use: Locations where ET intubation may be performed

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Todd D. Courtney -S
2014.06.05 15:19:37 -04'00'